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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,276	08/22/2005	Robyn O'Hehir	DAVI188.002APC	9537

20595 7590 03/19/2008

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EXAMINER	
ROONEY, NORA MAUREEN	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
03/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/510,276	O'HEHIR ET AL.	
	Examiner	Art Unit	
	PHUONG HUYNH	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,11-40 and 45-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-2, 4-9, 11-40, and 45-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

I. Claims 1-2, 4-9, 11-40, and 45-52 are pending.

Election/Restriction

II. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Invention 1 Claims 1, 2, 4-9, 11-37, 45 and 48, drawn to an isolated **peptide** comprising a Lol p1 T cell epitope, a pharmaceutical composition comprising said peptide and a kit comprising said peptide.

Invention 2 Claims 38, 50, and 52 drawn to an isolated **nucleic acid molecule** comprising a nucleotide sequence encoding an isolated peptide comprising a Lol p1 T cell epitope, a pharmaceutical composition comprising said nucleic acid molecule and a kit comprising said nucleic acid molecule.

Invention 3 Claim 39 and 40, drawn to a **method for treatment and/or prophylaxis** of a condition in a subject comprising administering to said subject an effect amount of an isolated **peptide** comprising a Lol p1 T cell epitope.

Invention 4 Claims 46 and 47, drawn to a **method of diagnosing** or monitoring a condition in a mammal comprising screening for Lol p1and/or Lol p5 reactive T cells and/or antibodies utilizing an isolated **peptide** comprising a Lol p1 T cell epitope.

Invention 5 Claim 49, drawn to a **method for treatment** and/or prophylaxis of a condition in a subject comprising administering to said subject an effect amount of a **nucleic acid** encoding an isolated peptide comprising a Lol p1 T cell epitope.

Invention 6 Claim 51, drawn to a **method of diagnosing** or monitoring a condition in a mammal comprising screening for Lol p1and/or Lol p5 reactive T cells and/or antibodies **utilizing an isolated nucleic acid** molecule encoding an isolated peptide comprising a Lol p1 T cell epitope.

The inventions listed as Inventions 1-6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A same or corresponding technical feature shared among Inventions 1-6 is an isolated peptide comprising a Lol p1 T cell epitope comprising at least 5 contiguous amino acids of SEQ ID NO: 15. However, the reference of Larch et al. (WO 99/34826, published 07/15/1999) teaches such peptide. Larch et al. teach the Lolium sp. allergen 126385 Lol p1 comprising an amino acid sequence of 263 amino acids, where positions 132-151 of its amino acid sequence is 100% identical to SEQ ID NO: 15. See below the alignment of SEQ ID NO: 15 of the instant application to the Lolium sp. allergen 126385 Lol p1 of Larch et al.

Alignment of SEQ ID NO: 15 to Lolium sp. allergen 126385 Lol p1 of Larch et al.

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ID   AAY25598 standard; protein; 263 AA.
XX
AC   AAY25598;
XX
DT   15-JUN-2007  (revised)
DT   30-SEP-1999  (first entry)
XX
DE   Lolium sp. allergen 126385 Lol p 1 protein fragment.
XX
KW   Major histocompatibility complex; class II; desensitising; human;
KW   allergen; grass; tree; weed; pollen; fungi; mould; food; insect; sting;
KW   chiromidae; spider; mite; housefly; fruit fly; sheep blow fly; honeybee;
KW   screw worm fly; grain weevil; silkworm; bee moth; larvae; mealworm; cat;
KW   cockroach; beetle; dog; horse; cow; pig; sheep; rabbit; rat; guinea pig;
KW   mice; gerbil; vaccine; treatment; prevention; hypersensitivity.
XX
OS   Lolium sp.
XX
PN   WO9934826-A1.
XX
PD   15-JUL-1999.
XX
PF   11-JAN-1999;   99WO-GB000080.
XX
PR   09-JAN-1998;   98GB-00000445.
PR   21-SEP-1998;   98GB-00020474.
XX
PA   (IMCO-) IMPERIAL COLLEGE INNOVATIONS LTD.
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XX
PI   Larche M,  Kay AB;
XX
DR   WPI; 1999-458255/38.
DR   PC:NCBI; gil26385.
XX
PT   Desensitizing patients to polypeptide allergens.
XX
PS   Example 6; Page 55; 117pp; English.
XX
CC   This invention describes a novel method of desensitizing a patient to a
CC   polypeptide allergen and comprises administering to the patient a peptide
CC   derived from the allergen where restriction to a MHC Class II molecule
CC   possessed by the patient can be demonstrated for the peptide and the
CC   peptide is able to induce a late phase response in an individual who
CC   possesses the MHC Class II molecule. The methods can be used for
CC   desensitising patients to allergens present in e.g. grass, tree and weed
CC   (including ragweed) pollens, fungi and moulds, foods, stinging insects,
CC   the chiromidae (non-biting midges), spiders and mites, housefly, fruit
CC   fly, sheep blow fly, screw worm fly, grain weevil, silkworm, honeybee,
CC   non-biting midge larvae, bee moth larvae, mealworm, cockroach, larvae of
CC   Tenibrio molitor beetle, mammals such as cat, dog, horse, cow, pig,
CC   sheep, rabbit, rat, guinea pig, mice or gerbil. They can also be used to
CC   produce immunological vaccines which may be used to prevent and/or treat
CC   conditions involving hypersensitivity to allergens. This sequence
CC   represents the Lolium sp. allergen 126385 Lol p1
CC
CC   Revised record issued on 15-JUN-2007 : Enhanced with precomputed
CC   information from BOND.
XX
SQ   Sequence 263 AA;

  Query Match             100.0%;  Score 103;  DB 2;  Length 263;
  Best Local Similarity   100.0%;  Pred. No. 3.8e-09;
  Matches   20;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy           1 GHAFGSMAKKGEEQNVRSAG 20
               ||||||||||||||||||||
Db         132 GHAFGSMAKKGEEQNVRSAG 151
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Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions 1-6 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

III. Accordingly, Groups 1-6 are not so linked as to form a single general inventive concept and restriction is proper.

IV. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

V. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all claims to the elected product claim are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VI. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

VII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Primary Examiner, Art Unit 1644
March 3, 2008